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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,762	02/09/2001	James R. Connor	P04864US2	6610

27407 7590 01/08/2002

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[REDACTED] EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1656	8

DATE MAILED: 01/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/780,762	CONNOR ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 August 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 and 24-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 6) filed on October 15, 2001 has been entered.
2. The Information Disclosure Statement (Paper No. 3) filed on August 8, 2001 has been entered.

Response to Arguments

3. Applicant's response to the office action (Paper No.) is fully considered and deemed persuasive in part.
4. The objection made in the previous office action is withdrawn herein in view of applicants' amendment (Paper No. 6).
5. The rejection made under 35 U.S.C. 112 first paragraph and second paragraph in the previous office action, is withdrawn herein in view of the applicants' amendment (Paper No.6).
6. Applicant's arguments with respect to the rejection under 35 U.S.C. 103(a) for claims 1-7, 10-12, 18-19, 21-25 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

Method claims require a last step or phrase in the last step that states the accomplishment of the goals for the method, which were stated in the method's preamble. Claim 20 lacks such a last step (how a PCR amplification of circularized cDNA is achieved using nucleotide primers) and is confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. App. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

a. Claims 1, 3-4, 7, 12, 13, 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Silver et al. (USPN. 4,994,370).

Silver et al. teach a method for amplification of single stranded DNA molecules wherein Silver et al. teach that the method comprises (i) obtaining linear, single strand DNA sample, (ii) circularization of the single strand DNA, (iii) introducing first and second sequence specific primers and (iv) performing polymerase chain reaction (see column 11, lines 35-37, column 12, lines 1-36, and column 8, lines 43-67). Silver et al. further teaches use of DNA ligase to circularize the DNA molecules (see column 3, lines 66-68, and column 4, 26-29). Thus the disclosure of Silver et al. meets the limitations in the instant claims.

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b. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Clontech Catalog (Stratagene Catalog, page 100, 1994).

Stratagene Catalog teaches a kit for amplifying first strand cDNA wherein the kit comprises a DNA ligase, a DNA polymerase, a reverse transcriptase without RNase H, and four deoxynucleoside triphosphates (dNTP mix) and sequence specific primers (see page 100, column 1, flow chart, and column 2, lines 1-22). Thus the disclosure of Stratagene Catalog meets the limitations in the instant claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-20 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silver et al. (USPN. 4,994,370) and in view of Gerard et al. (Molecular Biotechnology, Vol. 8: 61-77, 1997).

Silver et al. teach a method for amplification of single stranded DNA molecules wherein Silver et al. teach that the method comprises (i) obtaining linear, single strand DNA sample, (ii) circularization of the single strand DNA, (iii) introducing first and second sequence specific primers and (iv) performing polymerase chain reaction (see column 11, lines 35-37, column 12, lines 1-36, and column 8, lines 43-67). Silver et al. further teaches use of DNA ligase to circularize the DNA molecules (see column 3, lines 66-68, and column 4, 26-29). However, Silver et al. did not teach reverse transcriptase without RNase H and primers with 4-35 contiguous bases.

Gerard et al. teach a method for first-strand cDNA synthesis using reverse transcriptase without RNase H (superscript II H⁻ RT) and gene specific primers with 12-18 nucleotide bases (see page 71, column 1, 1-48, page 72, column 2, lines 26-48 and page 73, column 1, lines 1-27). Gerard et al. further teach harvesting (analyzing) the first-strand product by gel electrophoresis (see page 72, column 1, lines 31-33).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of amplifying single-stranded circular DNA as taught by Silver et al. with the amplification of mRNA with RNase H⁻ reverse transcriptase as taught by Gerard et al. to achieve expected advantage of obtaining single strand nucleic acid because Silver et al. states that "amplification of specific exons, provides a way to rapidly search for mutations in patients in whom it is difficult to obtain mRNA for cDNA cloning" (see column 10, lines 1-5). One such alternative form of amplification of exons, expressly motivated by Gerard et al. is to obtain amplification of single strand mRNA because Gerard et al states that "reverse transcriptase catalyzes cDNA synthesis more efficiently in the

absence of RNase H" (see page 61, abstract, line 3). An ordinary practitioner would have been motivated to combine the method of amplifying circular single-strand nucleic acid with the method of obtaining full length cDNA of Gerard et al. in order to achieve the expected advantage of rapid and efficient amplification of single strand nucleic acids.

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Spc
Suryaprabha Chunduru
January 4, 2002

JF
JEFFREY FREDMAN
PRIMARY EXAMINER